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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,772	11/14/2003	Yoshihiro Mori	09496/0200199-US0	8762

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EXAMINER	
CRAIG, PAULA L	
ART UNIT	**PAPER NUMBER**
3761	

MAIL DATE	DELIVERY MODE
06/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,772	MORI ET AL.	
	Examiner	Art Unit	
	Paula L. Craig	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8 and 9* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 2, 2007 has been entered.

Response to Arguments

2. The rejections of Claims 4-6 are withdrawn as moot. Applicant's arguments with respect to Claims 1-3 have been considered but are moot in view of the new grounds of rejection.

3. Applicant argues that when the determined fluid reduction ratio differs from a desired ratio, the Brugger device adjusts a flow restrictor or changes the flow rate to eliminate the difference, rather than reporting a trouble condition. The claims do not require that the system not include a flow restrictor, nor that the blood flow rate be held constant. The device of Brugger is described as reporting leaks and other trouble conditions (col. 6, lines 53-59, col. 7, lines 39-43, col. 24, lines 35-45, col. 26, lines 7-11, col. 31, lines 9-18; note that Applicant's specification teaches that leaks are one of the trouble conditions to be detected by the sensors, see specification, pages 13 and 31).

Brugger teaches the hematocrit sensors in the arterial and venous blood circuits as comparing the measured fluid reduction value with the theoretical value, and using the flow restrictor to zero out the difference (col. 24, lines 21-34). In light of Brugger's teaching of reporting leaks and other trouble conditions, it would be obvious where the difference between the measured values and the theoretical value was greater than expected, such as greater than a flow restrictor could reasonably achieve, to signal a problem in the system.

4. Applicant argues that the claimed mechanisms provide the advantage of simplifying over prior art systems requiring additional pressure sensors to detect a degradation in the performance of the blood pump and/or blood purifier. However, the claims do not contain limitations as to the maximum number of pressure sensors in the system.

Election/Restrictions

5. Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim 9 is part of Group II. Group II is described in the prior Office Action mailed May 25, 2006. Election was made **without** traverse in the reply filed on August 25, 2006.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification does not teach the reporting unit reporting a trouble condition for the blood purifier when the difference between the first measurement value and the first theoretical value is approximately equal to the difference between the second measurement value and the second theoretical value.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brugger.

10. For Claim 1, Brugger teaches a blood purification device having a blood circuit with an arterial blood circuit and a venous blood circuit (Fig. 11, col. 1, lines 15-17, and col. 9, line 24 to col. 10, line 24). A blood pump is disposed in the arterial blood circuit (blood pump 92, Fig. 11, col. 10, lines 1-17). A blood purifier is connected between the arterial blood circuit and the venous blood circuit, and configured to purify blood flowing in the blood circuit (hemofilter 34, Fig. 11 and col. 5, lines 58-64). A first measuring unit is disposed in the arterial blood circuit configured to measure the blood concentration of

the arterial blood circuit (upstream sensor measuring pre-treatment hematocrit, col. 24, lines 8-14). A second measuring unit is disposed in the venous blood circuit and configured to measure a blood concentration of the venous blood circuit (downstream sensor for post-treatment hematocrit, col. 24, lines 14-21). Brugger teaches a calculating unit configured to calculate a first measurement value and a first theoretical value, the first measurement value referring to a ratio of the blood concentrations measured by the first measuring unit and the second measuring unit (col. 24, lines 21-34, col. 30, lines 30-49). Brugger also teaches the first theoretical value referring to a blood concentration ratio obtained by a formula using a preset blood flow rate and the blood purifying rate of the blood purifier as parameters (col. 21, lines 24-53 and col. 24, lines 21-31). Brugger teaches an evaluation means (col. 21, line 1 to col. 22, line 59, col. 24, lines 21-43, col. 31, lines 9-18). Brugger teaches a reporting unit configured to report a trouble condition for at least one of the blood pump and the blood purifier when appropriate (col. 24, lines 35-45, col. 26, lines 7-11 and 30-52, col. 31, lines 9-18). Brugger teaches that the device is capable of detecting leaks (col. 6, lines 53-59, col. 7, lines 39-43; note that Applicant's specification teaches that leaks are one of the trouble conditions to be detected by the sensors, see specification, pages 13 and 31). Brugger does not expressly teach the evaluation unit evaluating whether a difference between the first measurement value and the first theoretical value is larger than a predetermined acceptable ratio difference, nor the reporting unit reporting this difference. Applicant's specification does not disclose that the evaluation unit evaluating whether a difference between the first measurement value and the first theoretical value

is larger than a predetermined acceptable ratio difference, nor the reporting unit reporting this difference serves any stated purpose or solves any particular problem as compared to the prior art. Various mathematical approaches exist for calculating whether a pair of sensors measuring a concentration are producing the expected results; the effectiveness of each approach from the patient or clinician's point of view depends not only on the precise mathematical formula used, but also on the limits considered tolerable. Applicant has not disclosed that the process of comparing ratios produces any differences from the prior art in terms of the number of sensors needed, the types or numbers of measurements required, or the concentrations provided in the device's output to the patient. It is well known in the art of feedback sensors to report a trouble condition when the theoretical values produced by a sensor do not match the expected results within certain limits. Given that Brugger teaches all the structural limitations of the claims, including a pair of measurement units measuring blood concentration in the arterial and venous blood circuits to detect leaks and other trouble conditions, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brugger to use ratio differences to calculate when the theoretical values differ enough from the measured values to determine that a trouble condition exists, and then report the trouble condition.

11. For Claim 2, Brugger teaches a blood purifier connected between the arterial blood circuit and the venous blood circuit (hemofilter 34, Fig. 11 and col. 5, lines 58-64). A water removing means is connected to the blood purifier for removing water from the blood flowing in the blood purifier (ultrafiltration and removal of waste fluid, col. 6, lines

43-60, col. 7, lines 26-30, col. 20, lines 41-67, col. 21, line 24 to col. 22, line 3, and col. 23, line 43 to col. 24, line 34). The purifying rate is the same as the water removal rate of the water removing means (col. 21, line 24 to col. 24, line 34).

12. For Claim 3, Brugger teaches a substitution fluid supplying means disposed to supply substitution fluid into the blood circuit (replacement fluid, col. 1, lines 37-42, col. 6, lines 1-7, and col. 20, lines 47-54). Brugger teaches a calculating means for calculating the ratio of the blood concentrations calculated as a theoretical value by the designated formula using the substitution fluid supplying rate preset for the substitution fluid supplying means and a filtration rate for the blood purifier in addition to the preset blood flow rate and the preset water removal rate as parameters (col. 6, lines 43-63, col. 20, line 41 to col. 22, line 59, and col. 23, line 43 to col. 24, line 34).

13. For Claim 8, Brugger teaches the blood pump being configured to adjust the preset blood flow rate to an adjusted blood flow rate (col. 21, lines 24-64). Brugger teaches the calculation unit being further configured to calculate a second measurement value and a second theoretical value, the measurement value referring to a ratio of the blood concentrations measured by the first measuring unit and the second measuring unit while the blood pump is operated at the adjusted blood flow rate and the blood purifier is operated at the preset blood purifying rate, and the theoretical value referring to a blood concentration ratio obtained by at least one formula based on parameters including the adjusted blood flow rate of the blood pump and the preset blood purifying rate of the blood purifier (col. 24, lines 21-45, col. 30, lines 30-49, col. 31, lines 42-67; note that measurement is continuous, rather than a one-time-only measurement, and

that the values of all the variables can be changed depending on which variable the user desires to hold constant; note also that the second theoretical value is not required by the claims to be different from the first theoretical value). Brugger teaches monitoring the performance of the device over time to verify the function and integrity of the pumps and the flow paths (col. 24, lines 38-43). Brugger does not expressly teach the evaluation unit being further configured to evaluate whether the difference between the first measurement value and the first theoretical value is approximately equal to a difference between the second measurement value and the second theoretical value. In light of Brugger's teaching of continuous monitoring and dynamic adjustment of the system, it would have been obvious to one of ordinary skill in the art to modify Brugger to include the evaluation unit being further configured to evaluate whether the difference between the first measurement value and the first theoretical value is approximately equal to a difference between the second measurement value and the second theoretical value, to determine whether conditions have deteriorated or a leak has started. Brugger also does not teach the reporting unit being configured to report the trouble condition for the blood purifier when the difference between the first measurement value and the first theoretical value is approximately equal to the difference between the second measurement value and the second theoretical value, and to report the trouble condition for the blood pump when the difference between the first measurement value and the first theoretical value is not approximately equal to the difference between the second measurement value and the second theoretical value. Given that Brugger teaches all the structural limitations of the claims, including a pair of

measurement units measuring blood concentration in the arterial and venous blood circuits to detect leaks and other trouble conditions, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brugger to use an appropriate method to calculate when the theoretical values differ enough from the measured values to determine that a trouble condition exists in the blood purifier or the blood pump respectively and report the trouble condition for each component, for the same reasons as described above for Claim 1 in paragraph 10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on M-F 8:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
Art Unit 3761

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